



SYSTEMATIC REVIEW & META-ANALISYS

Effectiveness of cartoons for children's procedural pain: a systematic review with meta-analysis

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Findings:

Cartoons show a very large and statistically significant positive effect on children's procedural pain and anxiety in comparison to standard of care.

ABSTRACT

BACKGROUND: Cartoons are widely used distraction techniques for nonpharmacological management of procedural pain in pediatric settings. There are a few studies in the literature evaluate the effect of intervention on procedural pain, but a systematic review aimed at providing a summary of the overall effect is lacking.

AIM: To summarize the available evidence on effectiveness of cartoons for children's procedural pain.

METHODS: Searching for parallel-group controlled trials was carried out on thirteen biomedical databases, five trial registries, web resources and gray literature sources from each database or resource setup date to 22 January 2023. Primary outcome was procedural pain, secondary outcome was anxiety. RoB 2 and ROBINS-I were used to assess risk of bias of included studies.

RESULTS: 24 trials were selected for this review, which included a total of 3046 pediatric subjects. Children who watch cartoons during medical procedures experience less pain (SMD = -1.29; 95% CI: -1.75, -0.83; N = 2239) and anxiety (UMD = -1.75; 95% CI: -2.94, -0.56; N = 552) compared to children provided standard of care; for both outcomes, results are statistically significant. GRADE method shows moderate certainty/quality of evidence.

CONCLUSIONS: Cartoons are more effective than standard of care in reducing procedural pain and anxiety in children. Pending future studies confirming the results, we recommend their implementation in daily clinical practice even in care settings with limited resources.

KEYWORDS: *Pain, Anxiety, Children, Cartoons, Meta-Analysis*

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1

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REVISIONE SISTEMATICA & META-ANALISI

Efficacia dei cartoni animati per il dolore procedurale dei bambini: una revisione sistematica con meta-analisi.

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Riscontri:

I cartoni animati mostrano un effetto positivo molto ampio e statisticamente significativo sul dolore e sull'ansia da procedura dei bambini rispetto allo standard di cura.

ABSTRACT

BACKGROUND: I cartoni animati sono una delle tecniche di distrazione utilizzate per la gestione non farmacologica del dolore procedurale in ambito pediatrico. Esistono alcuni studi in letteratura che valutano l'effetto dell'intervento sul dolore procedurale, ma manca una revisione sistematica volta a fornire una sintesi dell'effetto complessivo.

OBIETTIVO: Riassumere le prove disponibili sull'efficacia dei cartoni animati per il dolore procedurale dei bambini.

METODI: La ricerca di studi controllati a gruppi paralleli è stata effettuata su tredici database biomedici, cinque registri di studi, risorse web e fonti di letteratura grigia, dalla data di impostazione di ciascun database o risorsa al 22 gennaio 2023. L'outcome primario era il dolore procedurale, l'esito secondario era l'ansia. RoB 2 e ROBINS-I sono stati utilizzati per valutare il rischio di bias degli studi inclusi.

RISULTATI: Per questa revisione sono stati selezionati 24 studi, che includevano un totale di 3046 soggetti pediatrici. I bambini che guardano i cartoni animati durante le procedure mediche sperimentano meno dolore (SMD = -1,29; IC 95%: -1,75, -0,83; N = 2239) e ansia (UMD = -1,75; IC 95%: -2,94, -0,56; N = 552) rispetto ai bambini a cui è stato fornito lo standard di cura; per entrambi gli outcome, i risultati sono statisticamente significativi. Il metodo GRADE mostra una moderata certezza/qualità dell'evidenza.

CONCLUSIONI: I cartoni animati sono più efficaci dello standard di cura nel ridurre il dolore procedurale e l'ansia nei bambini. In attesa che studi futuri confermino i risultati, raccomandiamo la loro implementazione nella pratica clinica quotidiana anche in contesti assistenziali con risorse limitate.

KEYWORDS: *Dolore, Ansia, Bambini, Cartoni Animati, Meta-Analisi*

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2

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BACKGROUND

It is estimated proportion of children admitted to hospital with pain is 50-80% [1, 2] and on average they experience 6.3 painful medical procedures per day [3]. They perceive procedural pain as one of the most stressful and frightening experiences ever [4] but its management is still suboptimal, despite availability of multiple proven strategies [5]. Alleviating physical and emotional pain and suffering during pediatric care is an ethical imperative, a child's right and a nursing responsibility [6-8].

As recommended by American Society for Pain Management Nursing, nurses should best manage pain before, during and after medical procedure [9]. Approach on children should include both pharmacological and non-pharmacological interventions, with the latter being used first [10] especially when the former have proven to be inadequate, such as for short-term procedures [11].

Non-pharmacological interventions aim, through reduction of discomfort and fear, to make procedural pain more tolerable [12, 13, 14]. They are mostly free of side effects, easy to access and implement and inexpensive [15-17], reduce use of analgesics [18] and can often be managed by nurses [19].

Among the most common non-pharmacological interventions, cognitive-behavioral interventions include techniques such as distraction [20-22]. Distraction operates on assumption that by focusing child's attention on something fun and attractive with involvement of five senses, child's ability to pay

attention to painful stimuli will be hindered, as will related distress and anxiety [4, 23]. Distraction can be active if children explicitly participate in proposed activity (e.g., video games) or passive if they are not directly involved, as in case of watching cartoons. This type of distraction has been shown to alleviate procedural pain in children, especially preschool children, and is as effective as common psychological interventions [10, 24].

There are several studies in literature that have evaluated effectiveness of cartoons on procedural pain in pediatric settings [25-31], but a systematic review summarizing benefit is lacking.



OBJECTIVE

To summarize the available evidence on effectiveness of cartoons for children's procedural pain.

METHODS

To achieve this goal, a systematic review with meta-analysis was carried out. Review protocol was registered with International Prospective Register of Systematic Reviews (PROSPERO) (ID: CRD42023394663). Study was conducted and presented in accordance with PRISMA guidelines [32].



Eligibility criteria

Inclusion criteria were as follows: (1) participants: subjects aged 0-18 years undergoing medical procedures (excluding dental procedures); (2) intervention: watching cartoons during procedure via any type of media (e.g. TV, PC, tablet, smartphone); (3) control: standard of care, other intervention; (4) outcome: (a) primary - pain as measured by an observer or reported by child, (b) secondary - anxiety as measured by an observer or reported by child; (5) study design: randomized, quasi-randomized or non-randomized controlled clinical trials in parallel groups.

Information sources and search strategy

Biomedical databases The Cochrane Library, PubMed, EMBASE, CINAHL, PsycINFO, Web of Science, Scopus, AMED, LILACS, CNKI, SciELO, J-GLOBAL and J-STAGE were queried. Record search was performed from each setup database to 22 January 2023. Web resources The British Library - Main catalog, The Canadian Agency for Drugs and Technologies in Health - Gray Matters, Gray Literature Report, GrayGuide, ProQuest Dissertations & Theses, Mednar, OAIster, BASE, TRIP Medical Database, Google Scholar and clinical trial registries ICTRP, ClinicalTrials.gov, EU Clinical Trials Register, ISRCTN and PACTR were consulted. Following keywords with their synonyms were used: anxiety, cartoons, child, pain (Table S1). References of both eligible studies and reviews relevant to the topic were analyzed. Corresponding authors of

included studies were contacted by e-mail to determine if they were aware of any other studies of potential interest. No language or publication date limits were set.

Study selection and data extraction

After creation and common sharing of search strategy, all authors independently queried sources of information by removing duplicates and then selecting records according to title and abstract or, in doubtful cases, after full-text analysis. Records were managed using a Microsoft Excel spreadsheet. Any disagreements were resolved through comparison and discussion. From each included study, all authors independently extracted following main characteristics using a standardized and shared template: first author and year of publication; country and study design; type of procedure; sample characteristics; exclusion criteria; intervention and control characteristics; primary outcome and assessment tools; other outcomes.

Risk of bias

Independently, some authors (LGR, MD, VA and SCR) assessed the risk of bias with RoB 2 [33] for randomized or quasi-randomized studies and ROBINS-I [34] for non-randomized studies. Any disagreement was resolved through comparison and discussion; if necessary, the diriment opinion of other author (VT) was sought.

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Data analysis and synthesis

Three authors (LGR, MD and VA) extracted the data independently and resolved any differences of opinion through comparison and discussion. Variables of interest were sample size, mean and standard deviation of child pain and anxiety. In case of studies where median, range or interquartile range were present, conversion equations were used [35-37]. Overall effect size of intervention was calculated with unstandardized mean difference (UMD) or standardized mean difference (SMD), operationalized through Cohen's *d*. Effect was considered small, moderate, large or very large according to *d* thresholds of 0.2, 0.5, 0.8 and 1.0, respectively [38]. Random-effects model meta-analyses were implemented and forest plots created in case of at least two studies for each outcome with ProMeta© version 3.0 software. A 95% confidence interval was considered as deviation from point estimate for each individual study and from estimated global value for aggregated studies. Presence of statistical heterogeneity ($p < 0.05$) between studies was highlighted with Cochran's Q-test [39] and quantified with Higgins' I^2 index [40]. Values of $I^2 \leq 30\%$, 30-60%, 60-90% or $> 90\%$ were assigned a low, moderate, high or very high level of heterogeneity, respectively [41].

Publication bias

Assessment of publication bias was performed with at least five studies by inspection of funnel plot [42] and

application of Trim and Fill method [43]. Objective assessment of publication bias was performed by implementing Egger test [44], Begg and Mazumdar test [45] and FailSafe N test [46].

Sensitivity analysis

A sensitivity analysis was carried out by regenerating meta-analysis after exclusion of non-randomized studies.

Additional analysis

Subgroup analyses were planned to assess effect of cartoons on procedural pain according to gender and age of participants, procedure, clinical setting.

Summary of findings

Some authors (LGR, MD, VA and SCR) independently performed overall assessment of certainty/quality of evidence using the GRADE method [47] applied to meta-analysis results. Disagreements emerged were resolved by comparison and discussion or possible diriment opinion of other author (VT).

RESULTS

Selection of Studies

Figure 1 shows record selection process. Contact with corresponding authors of included studies did not reveal any additional studies. A total of 349 records were identified. Apart from duplicates and irrelevant





records after reading title and abstract, 37 studies were analyzed in full text and assessed for eligibility. Thirteen studies were excluded because they did not meet inclusion criteria [1, 6, 14, 48-57] (Table S2) while 24 were included in systematic review and quantitative synthesis [25-31, 58-74].

Characteristics of the studies

Studies included cover a time span of 20 years, from 2002 [25] to 2022 [58, 71, 72] (Table S3). Eight studies were conducted in India [28, 61, 63, 64, 66, 68, 69, 72], five in Turkey [30, 58, 65, 67, 71], three in Italy [59, 60, 62], two in South Korea [29, 74], one in Canada [25], Iran [26], United States [27], Spain [70], South Africa [73] and China [31]. Six studies were non-randomized [61, 63, 66, 69, 70, 74], one quasi-randomized [28] and the others randomized. Thirteen studies evaluated effectiveness of intervention during phlebotomy and/or intravenous cannula insertion [30, 31, 58-60, 63, 65, 66, 67-70, 74], six during immunization [25, 28, 61, 62, 64, 72], two during dressing changes [26, 71], one during wound suturing [29] and two during different medical procedures [27, 73]. Subjects were recruited from outpatient clinic [25, 28, 30, 58-64, 67, 72], ward [26, 31, 66, 68, 69, 71] and emergency room [27, 29, 65, 70, 73, 74]. A total of 3046 children were recruited in studies, with a mean age ranging from 1.34 years [61] to 9.1 years [67] and a proportion of males ranging from 38.4% [27] to 70% [74]. Percentage of subjects with experience in medical procedures ranged between 6.2% [71, 73] and 96.6% [60], that of participants with

previous hospitalization between 16.7% [69] and 61.7% [63]. Eight studies had two interventions and one control group [26, 28, 31, 59, 65, 67, 71, 73] and two had three interventions and one control group [30, 60]. Control group received standard of care, i.e., generally comfort and verbal support from parents and/or caregivers. Children were able to watch cartoons for at least entire duration of the procedure. Alternative interventions to cartoons were very heterogeneous, including active distraction by mother [59], children's songs [26], animated videos about procedure [65], video games [30] and psychological interventions [31]. Most common exclusion criteria was critical clinical conditions, acute pain, chronic illness, visual or hearing impairment, neurocognitive developmental disorders or delay. All studies had procedural pain as primary outcome; assessment tools used most frequently were WBFPRS [75] and FLACC [76]. Four studies assessed child's anxiety or fear (these studies used same assessment tool, CFS [77]) [30, 65, 67, 71] and three distress [62, 70, 73]. Other outcomes were child's pain or anxiety as perceived by parents or carers. [25, 29, 30, 59, 60, 65, 67], anxiety of parents or carers [25, 30, 60, 67, 70] and physiological parameters such as heart rate [26, 65, 70, 73, 74], blood pressure [65], arterial blood oxygen saturation [26, 65], blood glucose levels [74] and blood [74] or salivary [29] cortisol levels. Except in one study [70], at least one parent was always present during procedure and except in one case [26] children were not given analgesics or sedatives before procedure.



No studies found any side effects associated with procedure.

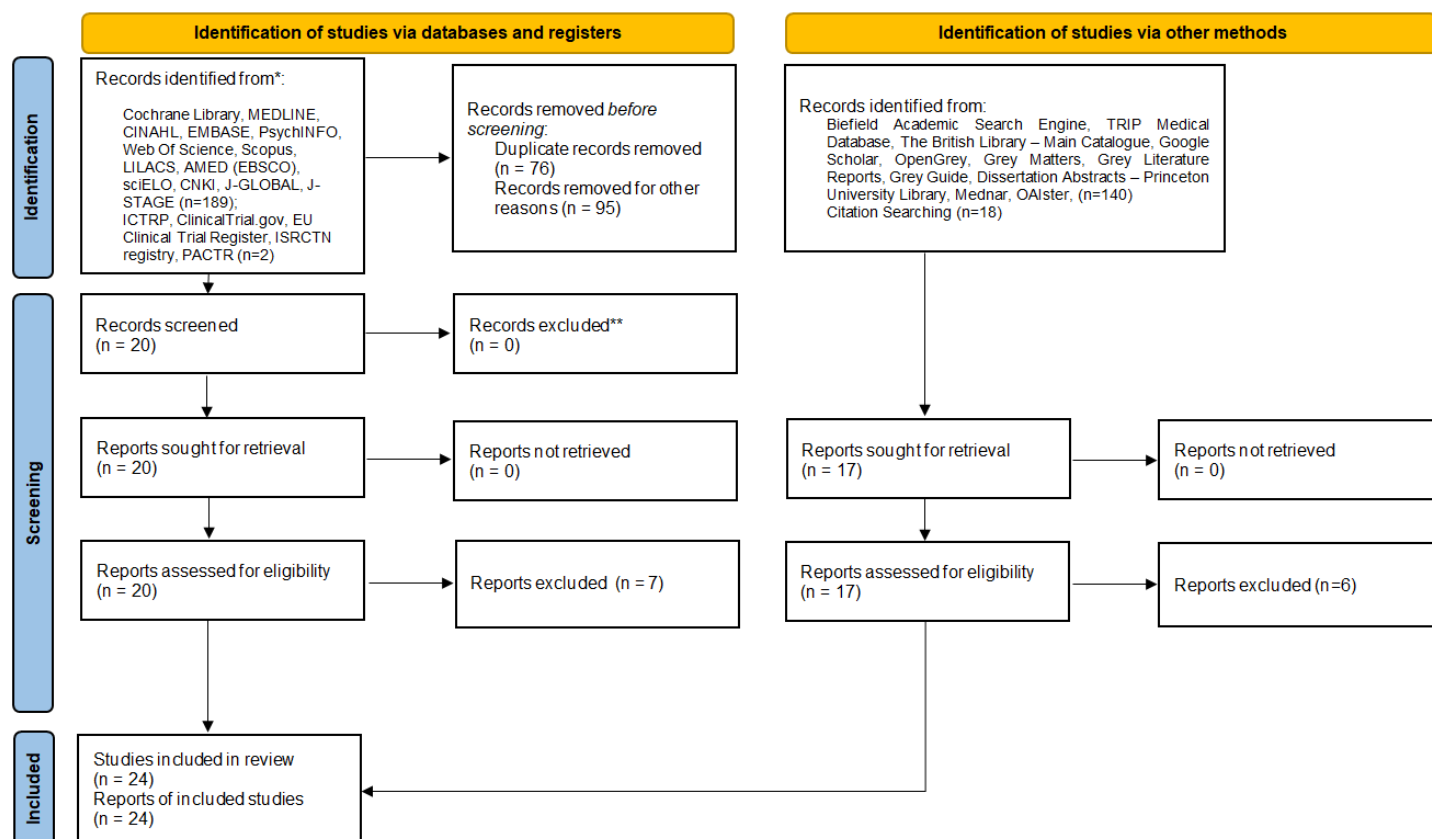


Figure 1: PRISMA flow diagram

Risk Of Study Bias

Quasi-randomized studies

For six studies, risk of bias is of some concern [29-31, 59, 62, 67]; for the others, risk of bias is high (Figure 2 and Figure 3).

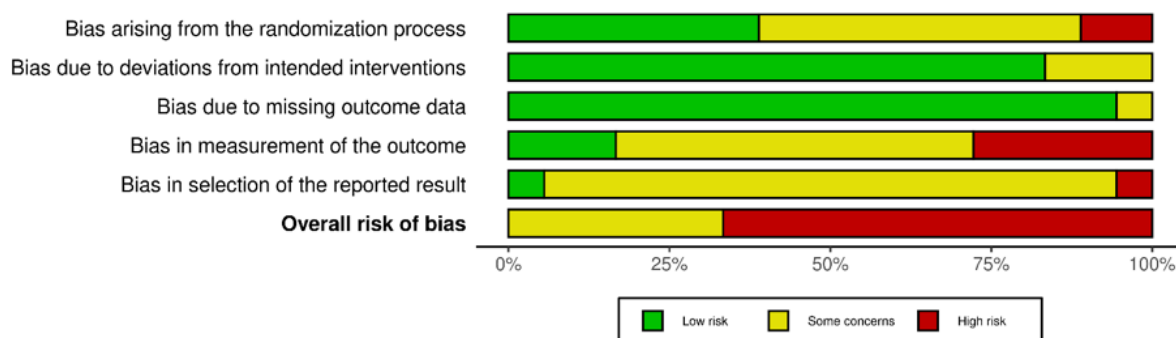


Figure 2: RoB 2 summary

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Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Akgül 2022	+	+	+	×	-	×
Bellieni 2006	-	+	+	+	-	-
Bergomi 2018	+	+	+	+	×	×
Cassidy 2002	-	+	+	-	-	×
Cerne 2015	-	+	+	+	-	-
Cheraghi 2021	-	+	+	-	-	×
Daniel 2017	-	-	+	×	-	×
Downey 2012	-	+	+	-	-	×
Düzkaaya 2021	-	+	+	×	-	×
Gedam 2013	×	+	+	×	-	×
Ha 2013	+	+	+	-	-	-
Inan 2019	+	+	+	-	-	-
Inangil 2020	+	+	+	-	+	-
Miguez.Navarro 2016	-	-	+	-	-	×
Özsoy 2022	-	+	+	-	-	×
Thomas 2022	×	+	+	×	-	×
Van der Heijden 2019	+	-	-	-	-	×
Wang 2008	+	+	+	-	-	-

Domains:
 D1: Bias arising from the randomization process.
 D2: Bias due to deviations from intended intervention.
 D3: Bias due to missing outcome data.
 D4: Bias in measurement of the outcome.
 D5: Bias in selection of the reported result.

Judgement
 × High
 - Some concerns
 + Low

Figure 3: RoB 2 traffic light

Non-randomized studies

All studies [61, 63, 66, 68, 69, 74] have a serious risk of bias (Figure 4 and Figure 5).

Study	Risk of bias domains							Overall
	D1	D2	D3	D4	D5	D6	D7	
Bijmool 2020	×	+	×	+	+	×	-	×
Chavan 2021	×	+	×	+	+	×	-	×
Gupta 2014	×	+	×	+	+	×	-	×
Lobo 2013	×	+	×	+	+	×	-	×
Maharajan 2017	×	+	×	+	+	×	-	×
Yoo 2011	×	+	×	+	+	×	-	×

Domains:
 D1: Bias due to confounding.
 D2: Bias due to selection of participants.
 D3: Bias in classification of interventions.
 D4: Bias due to deviations from intended interventions.
 D5: Bias due to missing data.
 D6: Bias in measurement of outcomes.
 D7: Bias in selection of the reported result.

Judgement
 × Serious
 - Moderate
 + Low

Figure 4: ROBINS-I traffic light

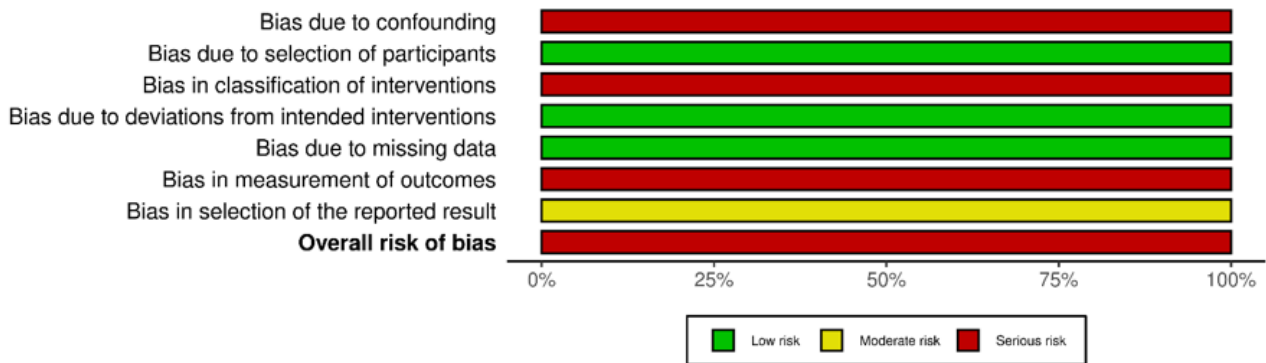


Figure 5: ROBINS-I summary

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Primary outcome

Procedural pain

Analysis of the effect of cartoons versus standard of care included 2239 participants. SMD (95% CI) for procedural pain score is -1.29 ([-1.75, -0.83], $I^2 = 95.57\%$) in favor of intervention in a statistically significant way (Table 1).

Study	Cartoons			Standard of care			Std. Mean Difference IV, Random, 95% CI	Weight	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Akgul 2022	0.73	1.39	41	3.80	3.19	40		4.05%	-1.25 [-1.73, -0.78]
Belliemi 2006	8.91	8.65	23	23.04	24.57	23		3.95%	-0.77 [-1.37, -0.17]
Bergomi 2018	1.45	2.00	37	2.10	2.00	39		4.07%	-0.40 [-0.85, 0.06]
Bijimol 2020	7.17	1.21	30	10.97	0.93	30		3.75%	-3.52 [-4.33, -2.71]
Cassidy 2002	1.36	1.39	31	2.03	1.80	28		4.02%	-0.42 [-0.94, 0.10]
Cerne 2015	3.30	2.20	18	4.30	2.30	17		3.89%	-0.44 [-1.12, 0.23]
Chavan 2021	2.30	0.46	30	2.90	0.25	30		3.97%	-1.62 [-2.20, -1.04]
Cheraghi 2021	2.10	1.12	40	4.62	1.40	40		4.01%	-1.99 [-2.52, -1.45]
Daniel 2017	3.60	1.67	30	6.90	1.70	30		3.94%	-1.96 [-2.57, -1.34]
Downey 2012 3-5 yrs	3.00	1.99	21	3.80	2.39	13		3.86%	-0.33 [-1.03, 0.36]
Downey 2012 at least 6 yrs	2.93	1.91	23	2.96	2.45	42		4.03%	-0.01 [-0.52, 0.50]
Duzkaya 2021	0.30	0.88	159	4.14	1.11	159		4.12%	-3.83 [-4.20, -3.46]
Gedam 2013	2.79	1.14	120	6.20	1.11	110		4.12%	-3.03 [-3.41, -2.65]
Gupta 2014	2.43	1.09	35	3.86	0.43	35		4.00%	-1.73 [-2.27, -1.18]
Ha 2013	2.71	3.24	42	3.76	3.36	42		4.08%	-0.32 [-0.75, 0.11]
Inan 2019	3.02	2.94	45	5.11	3.78	45		4.09%	-0.62 [-1.04, -0.19]
Inangil 2020	4.55	3.44	40	4.95	3.65	40		4.08%	-0.11 [-0.55, 0.33]
Lobo 2013	5.90	1.99	30	8.70	1.25	30		3.96%	-1.69 [-2.27, -1.10]
Maharjan 2017	6.63	0.80	30	9.43	0.62	30		3.69%	-3.91 [-4.78, -3.05]
Miguez-Navarro 2016	3.18	1.72	70	5.74	2.48	70		4.13%	-1.20 [-1.56, -0.84]
Ozsoy 2022	1.63	1.56	32	3.56	1.74	32		4.01%	-1.17 [-1.70, -0.64]
Thomas 2022	6.12	1.93	41	8.00	1.47	41		4.06%	-1.10 [-1.56, -0.63]
van der Heijden 2019	4.55	2.26	35	5.22	2.53	30		4.04%	-0.10 [-0.59, 0.38]
Wang 2008	3.54	3.79	100	3.3	3.77	100		4.17%	-0.28 [-0.56, -0.00]
Yoo 2011	1.05	1.05	20	1.95	1.43	20		3.92%	-0.72 [-1.36, -0.08]
Total (95% CI)			1123			1116		100.00%	-1.29 [-1.75, -0.83]

Table 1: Children's procedural pain – cartoons VS standard of care.

Secondary outcome

Anxiety/fear

Analysis of the effect of cartoons versus standard of care included 552 participants. UMD (95% CI) for anxiety/fear score is -1.75 ([-2.94, -0.56], $I^2 = 97.81\%$) in favor of intervention in a statistically significant way (Table 2).

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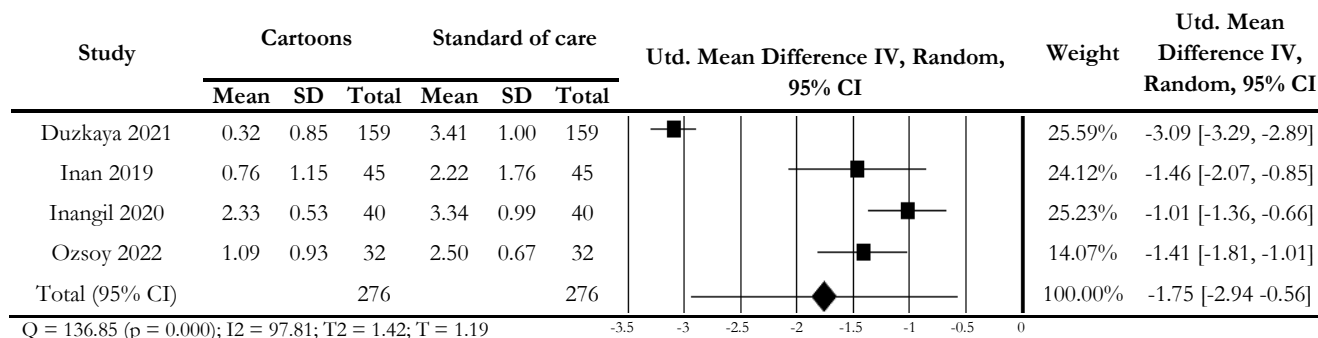


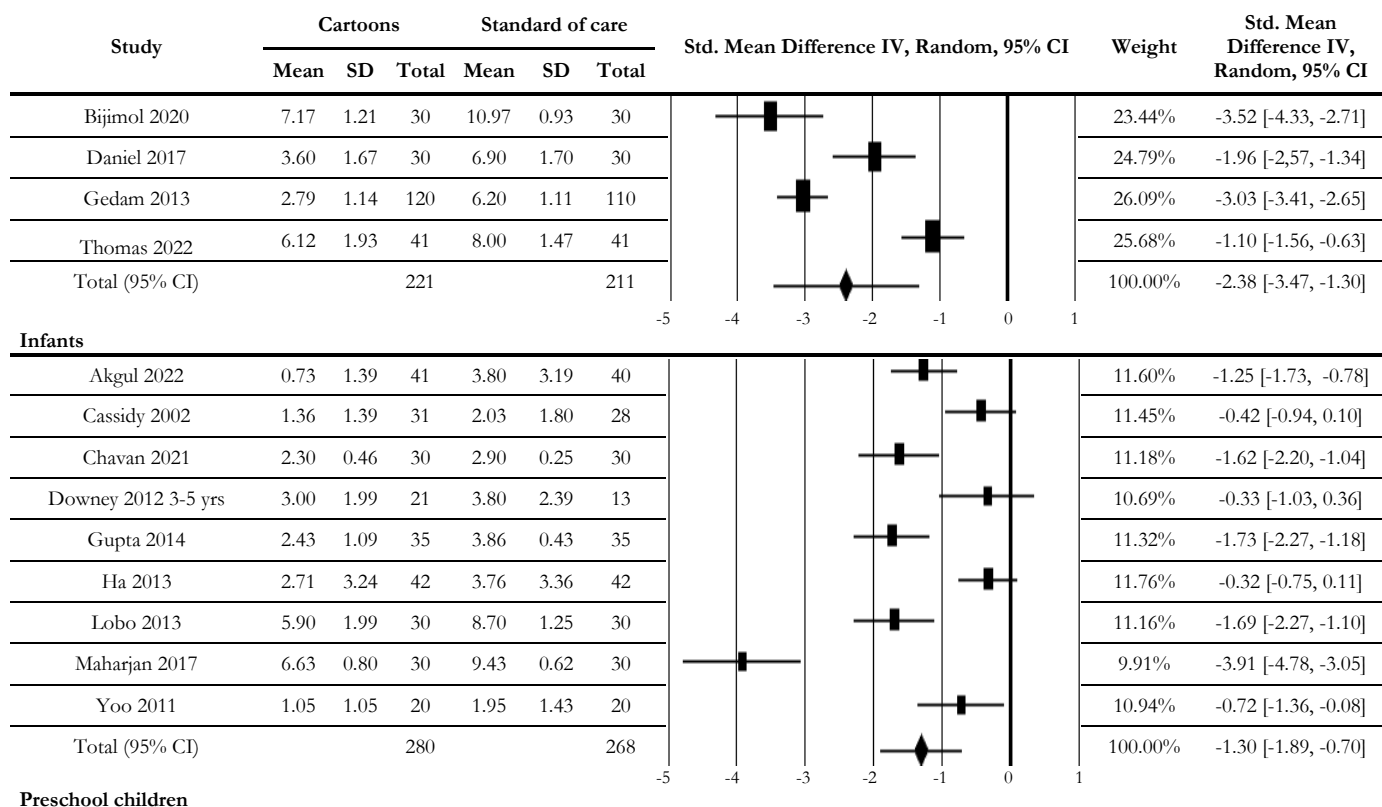
Table 2: Children's anxiety/fear – cartoons VS standard of care.

Additional analyses

Gender: No study performed effect of cartoons on procedural pain according to gender of participants.

Age: Depending on mean age of subjects, each study is assigned to subgroup 'infants' (0-2 years), 'preschool children' (3-5 years) or 'school children' (6-12 years). In subgroup 0-2 years SMD (95% CI) is -

2.38 ([-3.47, -1.30], I² = 94%; N = 432) in favor of intervention in a statistically significant way; in subgroup 3-5 years SMD (95% CI) is -1.30 ([-1.89, -0.70], I² = 89.79%; N = 548) in favor of intervention in a statistically significant way; in subgroup 6-12 years SMD (95% CI) is -0.91 ([-1.60, -0.23], I² = 96.58%; N = 1259) in favor of intervention in a statistically significant way (Table 3).



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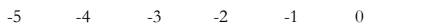


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Belliemi 2006	8.91	8.65	23	23.04	24.57	23	8.15%	-0.77	[-1.37, -0.17]
Bergomi 2018	1.45	2.00	37	2.10	2.00	39	8.37%	-0.40	[-0.85, 0.06]
Cerne 2015	3.30	2.20	18	4.30	2.30	17	8.02%	-0.44	[-1.12, 0.23]
Cheraghi 2021	2.10	1.12	40	4.62	1.40	40	8.25%	-1.99	[-2.52, -1.45]
Downey 2012 al least 6 yrs	2.93	1.91	23	2.96	2.45	42	8.29%	-0.01	[-0.52, 0.50]
Duzkaya 2021	0.30	0.88	159	4.14	1.11	159	8.47%	-3.83	[-4.20, -3.46]
Inan 2019	3.02	2.94	45	5.11	3.78	45	8.41%	-0.62	[-1.04, -0.19]
Inangil 2020	4.55	3.44	40	4.95	3.65	40	8.39%	-0.11	[-0.55, 0.33]
Míguez-Navarro 2016	3.18	1.72	70	5.74	2.48	70	8.49%	-1.11	[-1.46, -0.75]
Ozsoy 2022	1.63	1.56	32	3.56	1.74	32	8.26%	-1.17	[-1.70, -0.64]
Van der Heijden 2019	4.55	2.26	35	5.22	2.53	30	8.32%	-0.10	[-0.59, 0.38]
Wang 2008	3.54	3.79	100	3.3	3.77	100	8.57%	-0.28	[-0.56, -0.00]
Total (95% CI)			622			637	100.00%	-0.91	[-1.60, -0.23]



School children

Infants: Q = 49.97 (p = 0.000); I² = 94.00; T₂ = 1.14; T = 1.07

Preschool children: Q = 78.34 (p = 0.000); I² = 89.79; T₂ = 0.73; T = 0.86

School children: Q = 321.38 (p = 0.000); I² = 96.58; T₂ = 1.42; T = 1.19

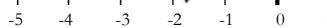
Table 3: Children’s procedural pain – cartoons VS standard of care (age)

Procedure

Depending on procedure performed, each study is assigned to subgroup 'immunization', 'other' or 'phlebotomy/peripheral venous catheter'. In immunization subgroup, SMD (95% CI) is -1.74 ([-2.77, -0.70], I² = 95.46%; N = 526) in favor of

intervention in a statistically significant way; in 'other' subgroup, SMD (95% CI) is -0.65 ([-1.26, -0.04], I² = 87. 95%; N = 392) in favor of intervention in a statistically significant way; in phlebotomy/peripheral venous catheter subgroup, SMD (95% CI) is -1.38 ([-2.05, -0.71], I² = 96.36%; N = 1321) in favor of intervention in a statistically significant way (Table 4).

Study	Cartoons			Standard of care			Std. Mean Difference IV, Random, 95% CI	Weight	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Bijimol 2020	7.17	1.21	30	10.97	0.93	30		15.91%	-3.52 [-4.33, -2.71]
Cassidy 2002	1.36	1.39	31	2.03	1.80	28		16.88%	-0.42 [-0.94, 0.10]
Cerne 2015	3.30	2.20	18	4.30	2.30	17		16.40%	-0.44 [-1.12, 0.23]
Daniel 2017	3.60	1.67	30	6.90	1.70	30		16.58%	-1.96 [-2.57, -1.34]
Gedam 2013	2.79	1.14	120	6.20	1.11	110		17.21%	-3.03 [-3.41, -2.65]
Thomas 2022	6.12	1.93	41	8.00	1.47	41		17.01%	-1.10 [-1.56, -0.63]
Total (95% CI)			270			256		100.00%	-1.74 [-2.77, -0.70]



Immunization

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Cheraghi 2021	2.10	1.12	40	4.62	1.40	40	16.66%	-1.99 [-2.52, -1.45]
Downey 2012 3-5 yrs	3.00	1.99	21	3.80	2.39	13	15.31%	-0.33 [-1.07, 0.36]
Downey 2012 al least 6 yrs	2.93	1.91	23	2.96	2.45	42	16.87%	-0.01 [-0.52, 0.50]
Ha 2013	2.71	3.24	42	3.76	3.36	42	17.44%	-0.32 [-0.75, 0.11]
Ozsoy 2022	1.63	1.56	32	3.56	1.74	32	16.70%	-1.17 [-1.70, -0.64]
Van Der Heijden 2019	4.55	2.26	35	5.22	2.53	30	17.02%	-0.10 [-0.59, 0.38]
Total (95% CI)			193			199	100.00%	-0.65 [-1.26, -0.04]

Other

Akgul 2022	0.73	1.39	41	3.80	3.19	40	7.76%	-1.25 [-1.73, -0.78]
Bellieni 2006	8.91	8.65	23	23.04	24.57	23	7.59%	-0.77 [-1.37, -0.17]
Bergomi 2018	1.45	2.00	37	2.10	2.00	39	7.79%	-0.40 [-0.85, 0.06]
Chavan 2021	2.30	0.46	30	2.90	0.25	30	7.61%	-1.62 [-2.20, -1.04]
Duzkaya 2021	0.30	0.88	159	4.14	1.11	159	7.88%	-3.83 [-4.20, -3.46]
Gupta 2014	2.43	1.09	35	3.86	0.43	35	7.66%	-1.73 [-2.27, -1.18]
Inan 2019	3.02	2.94	45	5.11	3.78	45	7.82%	-0.62 [-1.04, -0.19]
Inangil 2020	4.55	3.44	40	4.95	3.65	40	7.80%	-0.11 [-0.55, 0.33]
Lobo 2013	5.90	1.99	30	8.70	1.25	30	7.60%	-1.69 [-2.27, -1.10]
Maharjan 2017	6.63	0.80	30	9.43	0.62	30	7.12%	-3.91 [-4.78, -3.05]
Miguez-Navarro 2016	3.18	1.72	70	5.74	2.48	70	7.89%	-1.20 [-1.56, -0.84]
Wang 2008	3.54	3.79	100	3.3	3.77	100	7.96%	-0.28 [-0.56, -0.00]
Yoo 2011	1.05	1.05	20	1.95	1.43	20	7.52%	-0.72 [-1.36, -0.08]
Total (95% CI)			660			661	100.00%	-1.38 [-2.05, -0.71]

Phlebotomy/Peripheral Venous Catheter

Immunization: $Q = 110.05$ ($p = 0.000$); $I^2 = 95.46$; $T_2 = 1.59$; $T = 1.26$

Other: $Q = 41.48$ ($p = 0.000$); $I^2 = 87.95$; $T_2 = 0.51$; $T = 0.72$

Phlebotomy/Peripheral Venous Catheter: $Q = 329.50$ ($p = 0.000$); $I^2 = 96.36$; $T_2 = 1.45$; $T = 1.20$

Table 4: Children's procedural pain – cartoons vs standard of care (procedure)

Setting

Depending on participant recruitment setting, each study is assigned to subgroup 'outpatient clinic', 'emergency room' or 'ward'. In outpatient clinic subgroup SMD (95% CI) is -1.26 [-1.86, -0.65], $I^2 = 94.14\%$; $N = 959$) in favor of intervention in a statistically significant way; in emergency department

subgroup SMD (95% CI) is -0.94 [-2.10, 0.23], $I^2 = 97.68\%$; $N = 746$) in favor of intervention in a statistically nonsignificant way; in ward subgroup SMD (95% CI) is -1.75 [-2.65, -0.85], $I^2 = 94.65\%$; $N = 534$) in favor of intervention in a statistically significant way (Table 5).

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Study	Cartoons			Standard of care			Std. Mean Difference IV, Random, 95% CI	Weight	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Akgul 2022	0.73	1.39	41	3.80	3.19	40		8.47%	-1.25 [-1.73, -0.78]
Bellieni 2006	8.91	8.65	23	23.04	24.57	23		8.22%	-0.77 [-1.37, -0.17]
Bergomi 2018	1.45	2.00	37	2.10	2.00	39		8.51%	-0.40 [-0.85, 0.06]
Bijimol 2020	7.17	1.21	30	10.97	0.93	30		7.71%	-3.52 [-4.33, -2.71]
Cassidy 2002	1.36	1.39	31	2.03	1.80	28		8.39%	-0.42 [-0.94, 0.10]
Cerne 2015	3.30	2.20	18	4.30	2.30	17		8.05%	-0.44 [-1.12, 0.23]
Chavan 2021	2.30	0.46	30	2.90	0.25	30		8.25%	-1.62 [-2.20, -1.04]
Daniel 2017	3.60	1.67	30	6.90	1.70	30		8.18%	-1.96 [-2.57, -1.34]
Gedam 2013	2.79	1.14	120	6.20	1.11	110		8.63%	-3.03 [-3.41, -2.65]
Inan 2019	3.02	2.94	45	5.11	3.78	45		8.56%	-0.62 [-1.04, -0.19]
Inangil 2020	4.55	3.44	40	4.95	3.65	40		8.54%	-0.11 [-0.55, 0.33]
Thomas 2022	6.12	1.93	41	8.00	1.47	41		8.49%	-1.10 [-1.56, -0.63]
Total (95% CI)			486			473		100.00%	-1.26 [-1.86, -0.65]
Outpatient clinic									
wney 2012 3-5 yrs	3.00	1.99	21	3.80	2.39	13		13.96%	-0.33 [-1.03, 0.36]
Downey 2012 al least 6 yrs	2.93	1.91	23	2.96	2.45	42		14.29%	-0.01 [-0.52, 0.50]
Duzkaya 2021	0.30	0.88	159	4.14	1.11	159		14.48%	-3.83 [-4.20, -3.46]
Ha 2013	2.71	3.24	42	3.76	3.36	42		14.40%	-0.32 [-0.75, 0.11]
Míguez-Navarro 2016	3.18	1.72	70	5.74	2.48	70		14.49%	-1.20 [-1.56, -0.84]
Van der Heijden 2019	4.55	2.26	35	5.22	2.53	30		14.32%	-0.10 [-0.59, 0.38]
Yoo 2011	1.05	1.05	20	1.95	1.43	20		14.07%	-0.72 [-1.36, -0.08]
Total (95% CI)			370			376		100.00%	-0.94 [-2.10, 0.23]
Emergency Room									
Cheraghi 2021	2.10	1.12	40	4.62	1.40	40		16.82%	-1.99 [-2.52, -1.45]
Gupta 2014	2.43	1.09	35	3.86	0.43	35		16.77%	-1.73 [-2.27, -1.18]
Lobo 2013	5.90	1.99	30	8.70	1.25	30		16.61%	-1.69 [-2.27, -1.10]
Maharjan 2017	6.63	0.80	30	9.43	0.62	30		15.35%	-3.91 [-4.78, -3.05]
Ozsoy 2022	1.63	1.56	32	3.56	1.74	32		16.84%	-1.17 [-1.70, -0.64]
Wang 2008	3.54	3.79	100	3.3	3.77	100		17.60%	-0.28 [-0.56, -0.00]
Total (95% CI)			267			267		100.00%	-1.75 [-2.65, -0.85]
Ward									
Outpatient clinic: Q = 187.82 (p = 0.000); I ² = 94.14; T ₂ = 1.07; T = 1.03									
Emergency Room: Q = 258.40 (p = 0.000); I ² = 97.68; T ₂ = 2.40; T = 1.55									
Ward: Q = 93.46 (p = 0.000); I ² = 94.65; T ₂ = 1.17; T = 1.08									

Table 5: Children's procedural pain – cartoons vs standard of care (setting)

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Sensitivity analysis

After removal of non-randomized studies, SMD (95% CI) is -1.02 ([-1.54, -0.49], $I^2 = 96.06\%$; $N = 1889$) in favor of intervention in a statistically significant way.

Publication bias

Inspection of funnel plot (Figure 6) suggests publication bias is possible but unlikely. Indeed: (a)

Trim and Fill method identifies three asymmetrical studies, but estimated effect size (in black) is even larger than observed effect size (in white) (SMD = -1.46 vs SMD = -1.29); (b) Egger's test and Begg and Mazumdar's test are not statistically significant ($p = 0.563$ and $p = 0.135$ respectively); (c) Failsafe N value ($N = 3864$) is beyond safety limit ($N = 5k + 10 = 135$).

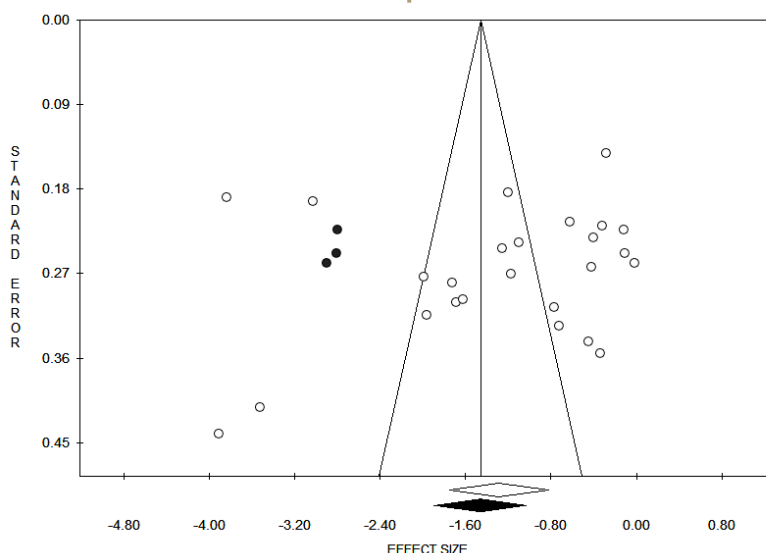


Figure 6: Funnel plot

Summary of findings

GRADE method shows moderate certainty/quality of evidence for the effect of cartoons on pain and anxiety/fear in children undergoing medical procedures (Table 6).

DISCUSSION

The objective of our systematic review was to summarize the available evidence on effectiveness of

cartoons for children's procedural pain. Results are in favor of intervention: the overall effect size for both outcomes is very large and statistically significant (SMD = -1.29 and UMD = -1.75 respectively). Level of certainty/quality of evidence is moderate: true effect is likely to be similar to estimated effect, but possibility exists that it is substantially different. Statistical heterogeneity between studies is very high ($I^2 > 90\%$) but no downgrading was performed because all studies are in favor of intervention.

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Summary of findings. Cartoons for children's procedural pain management

Cartoons compared to control for children's procedural pain and anxiety/fear

Patient or population: children (0-18 years) generally healthy undergoing medical procedure

Setting: any

Intervention: cartoons

Comparison: standard of care

Outcome:	Anticipated absolute effects* (95% CI)		N° participants (studies)	Certainty/quality of the evidence (GRADE)	Comments**
	Risk with standard of care	Risk with cartoons			
Children procedural pain	-	The mean level of procedural pain with cartoons was 1.29 standard deviation lower (1.75 lower to 0.83 lower).	2239 (18 qRCTs, 6 nRCTs)	⊕⊕⊕⊖ Moderate ^a	This result equates to a very large difference in favor of cartoons.
Children anxiety/fear	-	The mean level of children anxiety/fear with cartoons was 1.75 unstandard deviation lower (2.94 to 0.56 lower).	552 (4 qRCTs)	⊕⊕⊕⊖ Moderate ^a	This result equates to a very large difference in favor of cartoons.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

**0.2 represents a small difference, 0.5 a moderate difference, 0.8 a large difference and 1.0 a very large difference.

CI: confidence interval; qRCT: quasi randomized controlled trial; nRCT: non randomized controlled trial

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

^a Downgraded once for serious study limitations: most trials had unclear/high risk of bias in blinding, allocation concealment and/or selective reporting of outcomes.

Table 6: Children's procedural pain - cartoons VS standard of care (summary of findings)

Sensitivity analysis confirmed robustness of estimated effect size, which remained very large (SMD = -1.02) and statistically significant.

Subgroup analysis showed that: (a) as mean age of participants increases, benefit of intervention decreases (SMD = -2.38, SMD = -1.30, SMD = -0.91 for age groups 0-2 years, 3-5 years, 6-12 years respectively); (b) benefit of intervention is greatest for immunization and decreases for venipuncture/insertion of a peripheral venous

catheter or other procedures (e.g. dressing change, wound suturing) (SMD = -1.74, SMD = -1.38, SMD = -0.65 respectively); and (c) effectiveness of intervention is greatest on ward and decreases in outpatient clinic and emergency departments (SMD = -1.75, SMD = -1.26, SMD = -0.94 respectively).

Implications for practice

Due to the large total number of participants and given that studies were conducted in healthcare

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facilities in ten countries on four continents, it is reasonable benefit of cartoons on procedural pain could extend to similar clinical settings for medical procedures most frequently performed on children up to 12 years of age. There is less confidence in generalizability of effect on anxiety/fear, given that number of individuals is small, studies are few and all conducted in one country.

Lack of blindness may have overestimated benefit of intervention and, given incomplete or in some cases absent randomization, other variables not considered and unevenly distributed between the groups may have played a role on effect detected. Cartoons seem less effective on older children, for whom an active, more engaging distraction strategy may be preferable; these results are in line with literature data [48, 78]. Benefit of intervention seems to be reduced when procedure is long and complex, perhaps due to difficulty in maintaining distraction effect when pain lasts longer and is more intense. The greater effectiveness of intervention on ward may be because compared to outpatient clinic and emergency room this setting is less loaded with sensory stimuli that can counteract distracting power of cartoons.

One problem that remained unresolved even after subgroup analysis was very high statistical heterogeneity between studies. Sources of this heterogeneity could partly be due to chance and partly reflect methodological differences in recruitment of participants and conduct of studies: (a) children are distributed over a wide range in terms of age and

experience of hospitalization or procedure; (b) exclusion criteria are not uniform; (c) type and degree of parent-child interaction during procedure is not described; (d) characteristics of intervention (type of cartoon, choice or not between several options, freedom of choice of child, appropriateness according to neurocognitive development) differ. Duration of intervention also affects effectiveness: for an optimal effect, cartoons should start when child enters the room where the procedure will be performed and continue several minutes after its end [79, 80].

Most likely, main source of heterogeneity lies on difficulty of assessing pain in children, resulting in differences on intrinsic characteristics of measurement instruments and on way symptom is assessed. Factors that modify pain response include (a) physical, emotional, cognitive development and temperament; (b) fear, anxiety, anger, lack of control or choice; (c) underlying illness; (d) situational factors and previous experiences; (e) relationship between parent and child and former's reaction to latter's pain [15]; (f) adherence to social and cultural norms [17].

Implications for research

Future studies should be appropriately randomized and multicenter to achieve sufficient power to allow analysis by gender, age, ethnic group, procedure and setting. Characteristics of intervention do not allow for participant and practitioner blinding, but greater efforts could be made to ensure assessor blindness.





Limitations

Main limitations of review include low methodological quality, high risk of bias of most included studies and very high statistical heterogeneity between studies. In addition, due to extreme heterogeneity, a meta-analysis was not conducted to compare effect of cartoons with other interventions.

CONCLUSIONS

Cartoons show a very large and statistically significant positive effect on children's procedural pain and anxiety in comparison to standard of care. Pending further data from future studies confirming findings, we recommend their implementation in daily clinical practice even in care settings with limited resources.

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SUPPLEMENTARY MATERIAL:

TABLE S1: Search strategy (e.g., PubMed)

#1 Cartoon*	#2 Pain*	#11 Newborn*	#23 "Interventional study"
	#3 Suffering*	#12 Neonate*	#24 "Clinical Study"
	#4 Ache*	#13 Infant*	#25 "Clinical Trial"
	#5 Anxiet*	#14 Toddler*	#26 "Randomized Controlled Trial"
	#6 Angst*	#15 Baby	#27 "Randomised Controlled Trial"
	#7 Nervousness*	#16 Babies	#28 "Randomized Controlled Study"
	#8 Hypervigilance*	#17 Child*	#29 "Randomised Controlled Study"
	#9 Anxiousness*	#18 Adolescen*	#30 RCT
	#10 Fear*	#19 Youth*	#33 #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30
	#31 #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10	#20 Teen*	
		#21 Teenager*	
		#22 Minor*	
		#32 #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22	
#34 #1 AND #31 AND #32 AND #33			

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TABLE S2: excluded studies

REFERENCE	REASON FOR EXCLUSION
1. Bagnasco A, Pezzi E, Rosa F, Fornonil L, Sasso L (2012) Distraction techniques in children during venipuncture: an Italian experience. <i>J Prev Med Hyg</i> . PMID: 22803319	Lack of control group
2. Choi HJ, Kim HJ (2021) Efficacy of Cartoons as a Distraction Technique for Children Undergoing Suture of Facial Lacerations in the Emergency Department. <i>Pediatr Emerg Care</i> . https://doi.org/10.1097/PEC.0000000000001951	Lack of control group
3. Cohen LL, Blount RL, Panopoulos G (1997) Nurse coaching and cartoon distraction: an effective and practical intervention to reduce child, parent, and nurse distress during immunizations. <i>J Pediatr Psychol</i> . https://doi.org/10.1093/jpepsy/22.3.355	The intervention is composite, and cartoons constitute only a part of it
4. Crevatin F, Cozzi G, Braido E, Bertossa G, Rizzitelli P, Lionetti D, Matassi D, Calusa D, Ronfani L, Barbi E (2016) Hand-held computers can help to distract children undergoing painful venipuncture procedures. <i>Acta Paediatr</i> . https://doi.org/10.1111/apa.13454	The intervention consists of using a video game
5. Feng Z, Tang Q, Lin J, He Q, Peng C (2018) Application of animated cartoons in reducing the pain of dressing changes in children with burn injuries. <i>Int J Burns Trauma</i> . PMID: 30515348	RCT crossover
6. Ganesan R (2015) A study to compare the effectiveness of cartoon video distraction technique versus music therapy in altering behavior response to pain among toddler receiving immunization at pediatric outpatient department, Institute of child health and hospital, for children, Egmore, Chennai (Doctoral dissertation, College of Nursing, Madras Medical College, Chennai) http://repository-tnmgrmu.ac.in/10566/1/300216315ganesan.pdf	Cartoons + standard of care and music + standard of care are compared but a control group subjected only to the standard of care is missing
7. Hasanpour M, Tootoonchi M, Acin F, Yadegarfar G (2006) The effects of two non-pharmacologic pain management methods for intramuscular injection pain in children. <i>Acute Pain</i> . https://www.researchgate.net/profile/Ghasem-Yadegarfar/publication/244796982_The_effect_of_two_non-pharmacologic_pain_management_methods_for_intramuscular_injection_pain_in_children/links/5b2f3477a6fdec8506c77c3f/The-effect-of-two-non-pharmacologic-pain-management-methods-for-intramuscular-injection-pain-in-children.pdf	The intervention is not cartoons
8. James J, Ghai S, Rao KLN, Sharma N (2012) Effectiveness of “Animated Cartoons” as a distraction strategy on behavioural response to pain perception among children undergoing venipuncture. <i>Nurs Midwifery Res J</i> . https://www.researchgate.net/profile/Nitasha-Sharma-3/publication/336736943_Effectiveness_ofAnimated_Cartoons_as_a_distraction_strategy_on_behavioural_response_to_pain_perception_among_children_undergoing_venipuncture/links/5dafd40f92851c577eb9b97a/Effectiveness-ofAnimated-Cartoons-as-a-distraction-strategy-on-behavioural-response-to-pain-perception-among-children-undergoing-venipuncture.pdf	RCT crossover
9. Kaur B, Sarin J, Kumar Y (2014) Effectiveness of cartoon distraction on pain perception and distress in children during intravenous injection. <i>J Nurs Health Sci</i> . https://www.researchgate.net/profile/Yogesh-Kumar-29/publication/271256167_Effectiveness_of_cartoon_distraction_on_pain_perception_and_distress_in_children_during_intravenous_injection/links/5ace40e1aca2723a3341e611/Effectiveness-of-cartoon-distraction-on-pain-perception-and-distress-in-children-during-intravenous-injection.pdf	RCT crossover
10. Kuo HC, Pan HH, Creedy DK, Tsao Y (2018) Distraction-Based Interventions for Children Undergoing Venipuncture Procedures: A Randomized Controlled Study. <i>Clin Nurs Res</i> . https://doi.org/10.1177/1054773816686262	The outcome of interest is not procedural pain
11. MacLaren JE, Cohen LL (2005) A comparison of distraction strategies for venipuncture distress in children. <i>J Pediatr Psychol</i> . https://doi.org/10.1093/jpepsy/jsi062	The outcome of interest is not procedural pain
12. Sinha M, Christopher NC, Fenn R, Reeves L (2006) Evaluation of nonpharmacologic methods of pain and anxiety management for laceration repair in the pediatric emergency department. <i>Pediatrics</i> . https://doi.org/10.1542/peds.2005-1100	The intervention is composite, and cartoons constitute only a part of it
13. Ugucu G, Akdeniz Uysal D, Guzel Polat O, Artuvan Z, Polat Kulcu D, Aksu D, Gulgun Altintas M, Cetin H, Orekici Temel G (2022) Effects of cartoon watching and bubble-blowing during venipuncture on pain, fear, and anxiety in children aged 6-8 years: A randomized experimental study. <i>J Pediatr Nurs</i> . https://doi.org/10.1016/j.pedn.2022.03.016	There is a comparison between cartoons and another intervention but the control group undergoing standard care is missing

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TABLE S3: main characteristics of the included studies

Study (year)	Study design Country	Procedure	Setting	Sample	Exclusion criteria	Intervention	Control	Pain assessment tool	Other outcomes
Akgül (2022)	RCT Turkey	Phlebotomy	Outpatient clinic	N=81 (IG = 41, CG = 40), mean age 4.34 years, males 53% Previous experience of invasive procedures 91.4%	Children with chronic pain and neurocognitive developmental problems	Cartoon 3' before until 3' after the end of the procedure	Standard of care	WBFPRS, duration of crying	-
Bellieni (2006)	RCT Italy	Phlebotomy	Outpatient clinic	N=69 (IG 1 = 23, IG 2 = 23, CG = 23), mean age 8.67 years, males 47.8%	Children with verbal difficulties, neurodevelopmental delay, frequent venous punctures (more than 1 per year)	IG 1 - Cartoons 2' before the procedure and until its end IG 2 - Maternal distraction	Standard of care	OPS	Child's pain perceived by mother
Bergomi (2018)	RCT Italy	Phlebotomy	Outpatient clinic	N=150 (IG 1 = 37, IG 2 = 36, IG 3 = 38, CG = 39), mean age 8.93 years, males 40% Previous phlebotomy experience 96.6%	Children not able to understand Italian	IG 1 - Cartoons of the child's choice 2' before the procedure and until its end IG 2 - Buzzy® device IG 3 - Cartoons + Buzzy® device	Standard of care	WBFPRS	Child pain perceived by parents and nurses Child anxiety perceived by parents and nurses Parent anxiety
Bijmol (2020)	nRCT India	Immunization	Outpatient clinic	N=60 (IG = 30, CG = 30), mean age 1.34 years, males 63.3%	Not declared	Cartoons	Standard of care	r-FLACC	-
Cassidy (2002)	RCT Canada	Immunization (diphtheria, tetanus, polio, pertussis vaccine)	Outpatient clinic	N=62 (IG = 29, CG = 33), age 5 years, males 45.6%	Children with previous immunization with diphtheria, tetanus, polio, cough vaccine at pre-school age, previously hospitalized, with acute or chronic medical conditions	Cartoons - TV viewing starting just before the procedure until its end	Standard of care + watching a switched-off TV	FPS, CFCS, CHEOPS	Distraction effect of cartoons (watch needle vs watch TV) Child's anxiety perceived by parent Parent's anxiety
Cerne (2015)	RCT Italy	Two immunizations (the first subcutaneously - diphtheria, tetanus, whooping cough, polio, measles, mumps, rubella and varicella vaccine, the second intramuscularly - meningococcal vaccine)	Outpatient clinic	N=35 (IG = 18, CG = 17), age 6 years, males 51.5%	Children with developmental delay, severe speech difficulties, treated with anxiolytics, analgesics or narcotics, with distress or pain unrelated to the procedure	Cartoons of the child's choice 5' before the procedure and until its end	Standard of care	WBFPRS	Distress perceived by the child (Amended Observation Scale of Behavioural Distress - OSBD-A)

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Chavan (2021)	nRCT India	Phlebotomy	Outpatient clinic	N=60 (IG = 30, CG = 30), mean age 4.14 years, males 51.7% Previous hospitalization experience 61.7% Previous phlebotomy experience 61.7%	Children who are unconscious, mentally unaware, critically ill or cognitively impaired	Cartoons	SoC	r-FLACC	-
Cheraghi (2021)	RCT Iran	Dressing change on burn	Ward	N=120 (IG 1 = 40, IG 2 = 40, CG = 40), mean age 8.35 years, males 62.5% Average percentage of body surface area with burns 4%	Children with speech, sight, hearing or cognitive impairment, with neurological defects (e.g., neuropathy, limb paralysis), uncooperative, in critical condition, requiring pain medication during the procedure, with burns to eyes or ears	IG 1 - Cartoons 2' before the procedure and until its end IG 2 - Children's songs 2' before the procedure and until its end	Standard of care	OPS	Heart rate Percentage oxygen saturation (arterial blood)
Daniel (2017)	RCT India	Immunization	Outpatient clinic	N=60 (IG = 30, CG = 30), mean age 1.53 years, males 51.7%	Not declared	Cartoons	Standard of care	FLACC	-
Downey (2021)	RCT United States	Phlebotomy, insertion of intravenous cannula, wound suture, other medical procedures	Emergency room	N=99 (IG = 44, CG = 55), mean age 8.56 years, males 38.4%	Children in critical clinical conditions	Cartoons of child's choice	Standard of care	WBFPRS 3-5 years, PCS ≥ 6 years	-
Düzkaya (2021)	RCT Turkey	Insertion of intravenous cannula	Pediatric emergency room	N=477 (IG 1 = 159, IG 2 = 159, CG = 159), mean age 8.80 years, males 51.6%	Unconscious children, under the influence of sedatives, anticonvulsants, analgesics, with previous hospitalization, with chronic diseases or life-threatening conditions, in critical clinical condition	IG 1 - Cartoons of the child's choice IG 2 - Animated videos on how to perform the procedure	Standard of care	WBFPRS	Anxiety perceived by child (Children's Fear Scale - CFS) Pain perceived by parent or nurse Fear perceived by parent or nurse Blood pressure Heart rate Percentage oxygen saturation (arterial blood)
Gedam (2013)	qRCT India	Immunization	Outpatient clinic	N=350 (IG 1 = 120, IG 2 = 120, CG = 110), mean age 1.49 years, males 53.7%	Children with neurological disorders or chronic clinical conditions, who received treatment of any kind at a health facility before the study, who took analgesics in the last three hours before the procedure, who cried before the procedure, who had to undergo the procedure by subcutaneous injection	IG 1 - Cartoons IG 2 - Toy that generates light and sound	Standard of care	FLACC	-
Gupta (2014)	nRCT India	Phlebotomy, intravenous cannula insertion	Ward	N=70 (IG = 35, CG = 35), average age 4.17 years, males 60%	Unconscious children, under the influence of any sedative/anticonvulsant/analgesic medication, who have received a recent venous puncture or who have undergone any painful procedure	Cartoons	Standard of care	FLACC	-

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31

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Ha (2013)	RCT South Korea	Wound suture	Emergency room	N=84 (IG = 42, CG = 42), mean age 5.98 years, males 64.3% Previous experience of admission to an emergency room 58.3%	Children unable to communicate, with brain damage or verbal, visual or auditory disturbances, with chronic conditions, with lacerations longer than 5 cm and/or deeper than subcutaneous tissue alone, requiring treatment for fractures or multiple injuries, who were given analgesics or sedatives	Cartoons of the child's choice until the end of the procedure (pre- selection by the caregiver)	Standard of care	WBFPRS	Child's behaviour during the procedure (Procedure Behaviour Checklist - PBCL) Child's pain perceived by the parent Salivary cortisol levels
Inan (2019)	RCT Turkey	Phlebotomy	Outpatient clinic	N =180 (IG 1 = 45, IG 2 = 45, IG 3 = 45, CG = 45), mean age 7.77 years, males 49.4% Previous phlebotomy experience 92.8%	Children with cognitive, visual, hearing impairments	IG 1 - Cartoons of the child's choice 3' before the procedure and until its end IG 2 - Video game of the child's choice IG 3 = Parental comfort	Standard of care	r-WBFPRS	Anxiety perceived by the child (CFS) Pain perceived by the parent or nurse Anxiety perceived by the parent or nurse
Inangil (2020)	RCT Turkey	Phlebotomy	Outpatient clinic	N =120 (IG 1 = 40, IG 2 = 40, CG = 40), mean age 9.1 years, males 55% Previous phlebotomy experience 59.2%	Children with acute pain or anxiety at the time of the procedure, with audiovisual, cognitive or physical disabilities, unable to communicate by verbalising, with an incision or scar tissue in the forearm area, with congenital, genetic, developmental or neurological diseases, with problems with nutrition or hydration, with skin integrity, with involuntary arm movement	IG 1 - Cartoon of the child's choice 1' before the procedure and of 4' duration IG 2 - Cartoon in virtual reality of the child's choice 1' before the procedure and of 4' duration	Standard of care	WBFPRS	Anxiety perceived by the child (CFS) Pain perceived by the parent or nurse Anxiety perceived by the parent or nurse
Lobo (2013)	nRCT India	Phlebotomy	Ward	N=60 (IG = 30, CG = 30), mean age 4.67 years, males 48.3%	Disabled children with chronic illnesses, on whom two unsuccessful phlebotomy attempts had been made	Cartoon 5' before the procedure and until its end; total duration 15'	Standard of care	WBFPRS	-
Maharjan (2017)	nRCT India	Phlebotomy	Ward	N=60 (GI = 30, CG = 30), mean age 5.1 years, males 65% Previous phlebotomy experience 11.7% Previous experience of hospitalization 16.7%	Children admitted to intensive care with visual or hearing impairment	Cartoons	Standard of care	FLACC	-
Miguez- Navarro (2016)	RCT Spain	Phlebotomy, intravenous cannula insertion	Pediatric emergency room	N=140 (IG = 70, CG = 70), mean age 6.88 years, males 57.9% Experience of phlebotomy in the previous two months 16.4%	Children with psychomotor retardation, chronic illnesses, disturbance of consciousness, in critical clinical conditions	Cartoons of child's choice	Standard of care	WBFPRS 3-7 years, NRS > 7 years	Distress perceived by the child (Groningen Distress Scale - GDS) Parental anxiety Heart rate Level of difficulty of the procedure

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32

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Özsoy (2022)	RCT Turkey	Change of dressing on surgical wound for minor adominal surgery	Ward	N=96 (IG 1 = 32, IG 2 = 32, CG = 32), mean age 8.58 years, males 56.3% Previous experience of dressing changes 6.2%	Children with physical or mental health problems impeding communication, with a history of epilepsy, migraine or vestibular disease, who had received analgesics or sedatives in the last 6 hours	IG 1 - Cartoon 3' before the procedure and until its end IG 2 - Cartoon in virtual reality	Standard of care	WBFPRS	Fear perceived by the child (CFS)
Thomas (2022)	RCT India	Immunization	Outpatient clinic	N=82 (IG = 41, CG = 41), mean age 1.61 years, males 53.7%	Not declared	Cartoon 2' before the procedure and up to 2' after its completion	Standard of care	r-FLACC	-
van der Heijden (2019)	RCT South Africa	Phlebotomy, insertion of intravenous cannula, application of a splint or plaster cast, injection of local anaesthetic, wound dressing or suturing	Pediatric emergency room	N=191 (IG 1 = 62, IG 2 = 75, CG = 54), mean age 7.28 years, males 68% Previous dressing experience 6.2%	Children with hearing impairment, developmental disabilities, impaired level of consciousness	IG 1 - Cartoon IG 2 - Relaxing music	Standard of care	AHTPS 0-4 years, r-FPS > 4 years	Distress perceived by the child (revised Observation Scale of Behavioural Distress - rOSBD) Heart rate
Wang (2008)	RCT China	Phlebotomy	Ward	N=300 (IG 1 = 100, IG 2 = 100, CG = 100), mean age 8.45 years, males 48.7%	Children with impaired cognitive development or impaired cognitive status, visual and/or hearing impairment, history of stinging in the last three months, being treated with analgesic, anxiolytic or narcotic drugs in the last three days	IG 1 - Cartoons of the child's choice 3' before the procedure and until its end IG 2 - Psychological intervention (information about the procedure, therapeutic touch, encouragement, guided imagination)	Standard of care	VAS	Cooperative behaviour Duration of the procedure
Yoo (2011)	nRCT South Corea	Phlebotomy	Emergency room	N=40 (IG = 20, CG = 20), average age 4.51 years, males 70% Previous phlebotomy experience 57.5%	Children not fasting 4 hours before sampling, diabetes or other chronic diseases, delayed hearing or vision development, extreme pain from fractures or injuries from accidents	Cartoon with a running time of 3'	Standard of care	PCS, WBFPRS	Heart rate Serum glucose and cortisol levels

AHTPS=Alder Hey Triage Pain Score; CFCS=Child Facial Coding System; CG=Control Group; CHEOPS=Children's Hospital of Eastern Ontario Pain Scale; FLACC=Face, Legs, Activity, Crying, and Consolability scale; FPS=Faces Pain Scale; IG=Intervention Group; nRCT=non Randomized Controlled Trial; NRS=Numerical Rating Scale; OPS=Oucher Pain Scale; PCS=Poker Chips Scale; qRCT=quasi Randomized Controlled Trial; r-FLACC=revised Face, Legs, Activity, Crying, and Consolability scale; r-FPS=revised Faces Pain Scale; r-WBFPRS=revised Wong Baker Faces Pain Rating Scale; SoC=Standard of Care; VAS=Visual Analogue Scale; WBFPRS=Wong Baker Faces Pain Rating Scale.

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33

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